

**Claim Listing and Claim Amendments.** Please enter the following claim amendments:

1. (Currently Amended) An apparatus for detecting a body cavity of a subject, measuring the volume of the body cavity and a fluid volume contained in the body cavity the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising: a transducer assembly including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity at plural angles of incidence and/or from plural spatial locations; means for activating the transducers to produce transmitted ultrasound signals; means for detecting body cavity wall echoes from received ultrasound signals; means for determining, from said received signals, a body cavity height H and depth D; means for determining a specific measurement configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid filled body cavity to thereby select an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and means for calculating the fluid volume according to the formula  $H \times D \times K$

at least one transducer assembly positioned in view of the body cavity and configured to transmit ultrasound of at least one acoustic power having a fundamental frequency to the body cavity, receive echoes having a harmonic frequency and the fundamental frequency reflected from surfaces associated with the body cavity, and convert the fundamental and harmonic frequency echoes into fundamental and harmonic signals; and

a computer in signal communication with the at least one transducer assembly, the computer having executable signal processing software with programmed instructions to differentiate information from the fundamental and harmonic signals and to calculate the volume of the body cavity and the fluid volume contained in the cavity based upon image information derived from the harmonic signals.

2. (Currently Amended) The apparatus of claim 1, ~~wherein adapted for use where the~~ body cavity comprises a bladder and the ~~volume of fluid measured is a volume of the fluid~~ volume comprises urine.

3. (Currently Amended) The apparatus of claim 1, wherein the at least one transducer assembly includes a plurality of transducer assemblies positioned for transmitting and receiving echoes in which the means for activating includes means for transmitting said plurality of ultrasound signals in a selected order.

4. (Currently Amended) The apparatus of claim 1 ~~3~~, wherein the at least one acoustic power includes a first power to ascertain the subject's attenuation of echoes having the fundamental frequency and a second power to ascertain the conditions in which the subject generates echoes having at least one harmonic frequency of the fundamental frequency in which the means for detecting uses echo travel time and other beam information from the plurality of ultrasound signals.

5. (Currently Amended) The apparatus of claim 1 ~~4~~, wherein the programmed instructions are applied to the fundamental and harmonic signals derived from in which the means for determining selects specific ultrasound signals from the plurality of ultrasound signals corresponding to ultrasound beams that have intercepted the fluid filled of the body cavity.

6. (Currently Amended) The apparatus of claim 1 ~~5~~, wherein the programmed instructions include averaging signals associated with the first and second power acoustic powers, subtracting the fundamental signals associated with the first power from the harmonic signals associated with the second power to produce a difference signal further including display means for instantaneous display of the calculated fluid volume to allow optimisation of transducer positioning by the user.



7. (Currently Amended) The apparatus of claim 4, wherein the fluid volume is determined from comparing the difference signal to a calibration curve of the subject stored in memory of the computer in which the means for deriving includes a memory storing a plurality of empirically predetermined correction factors K.

8. (Currently Amended) The apparatus of claim 3, wherein the plurality of transducer assemblies includes an array of five including five transducers in the array.

9. (Currently Amended) The apparatus of claim 8, wherein in which the array of five transducers transducer assemblies are respectively oriented at angles OA, OB, OC, OD, OE, to an axis orthogonal to the plane of the transducer assemblies array, the angles being approximately OA = -25°, OB = 0°, OC = +25°, OD = +25°, OE = +40°.

10. (Currently Amended) The apparatus of claim 9, wherein in which the transducer assemblies array number of transducers is selected to yield only gross are configured to ascertain at least one of ranges of bladder filling or and to indicate a clinically important bladder filling level.

11. (Currently Amended) The apparatus of claim 10, wherein the at least one transducer assembly includes a display to present further including means to input patient information, for example including at least one of gender, weight, and age, to age, and select correction factors K derived from the calibration curve for use in the volume calculation.

12. (Currently Amended) The apparatus of claim 11, wherein the calibration curve includes provided with internal memory and means to input and store validated volume measurements to optimize correction factors K in a "self learning process".

13. (Currently Amended) The apparatus of claim 4 11, wherein volume information of the cavity or the fluid may be frozen via ~~provided with means to freeze the read-out with a hold/start button connected with the transducer assembly.~~

14. (Currently Amended) The apparatus of claim 4 3, wherein where the plurality of transducer assemblies ~~transducers~~ are positioned ~~in an assembly~~ so that the echo reflecting areas of the walls of the bladder are approximately located in a single cross-sectional sagittal plane.

15. (Currently Amended) The apparatus of claim 4 14, wherein in which the plurality of transducer assemblies ~~ultrasound transducers~~ are approximately disk-shaped.

16. (Currently Amended) The apparatus of claim 4 15, wherein the transducer assemblies are powered by ~~where the electric power can be provided by a battery.~~

17. (Currently Amended) The apparatus of claim 4 14, wherein the transducer assemblies are configured to display ~~further including means for indicating~~ correct caudal-cranial positioning of the transducer ~~assembly~~ assemblies over a human bladder.

18. (Currently Amended) The apparatus of claim 1, wherein ~~in which~~ the transducer assembly is connected with a cable to a housing containing an input device, a processor, a display and a power supply unit.

19. (Currently Amended) The apparatus of claim 1, wherein where the at least one transducer assembly further includes an ultrasound coupling material covering the transducers for optimal acoustic coupling and patient convenience.

20. (Currently Amended) A method for detecting a body cavity of a subject, measuring the volume of the body cavity and a fluid volume contained in the body cavity ~~the volume of~~



fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising the steps of : transmitting a plurality of ultrasonic beams into the region of the body containing the cavity at plural angles of incidence and/or from plural spatial locations; receiving a plurality of ultrasonic signals from the body; determining, from said received signals, a body cavity height H and depth D; determining, from the received signals, a specific measurement configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid-filled body cavity to thereby select an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and calculating the fluid volume according to the formula  $H \times D \times K$

positioning at least one transducer assembly in view of the body cavity;

transmitting a fundamental ultrasound frequency of at least one acoustic power to the body cavity;

receiving echoes having the fundamental ultrasound frequency and at least one harmonic frequency thereof associated with the body cavity;

converting the received ultrasound echoes into fundamental signals and harmonic signals;

determining boundary information of the cavity from the harmonic signals; and

calculating at least one of the volume of the cavity from the boundary information and the fluid volume in the body cavity.

21. (Currently Amended) The method of claim 20, wherein determining boundary information includes applying computer executable signal processing software with programmed instructions to differentiate information from the fundamental and harmonic signals further including the step of displaying the calculated volume on a display device.

22. (Currently Amended) The method of claim 20, wherein positioning includes an array of transducer assemblies configured to further including the step of transmitting the plurality of ultrasonic beams into the body subject from a transducer array in which a plurality of transducers are arranged with a predetermined spatial location and mounting angle.

23. (Currently Amended) The method of claim 20 22, wherein the array of transducer assemblies are further including the step of acoustically coupled coupling the transducers of the transducer array to the skin of the subject body being measured using an acoustic coupling material.

24 (Currently Amended) An apparatus for detecting a bladder of a subject, measuring the volume of the bladder and a fluid volume contained in the bladder the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising: one or more transducers for transmitting at least one ultrasound beam into the body such that the at least one beam encompasses a substantial portion of the target body cavity, the beam having at least a first frequency; means for receiving ultrasound echo signals from the body cavity and determining a measure of higher harmonic components of the first frequency in the received signals; and means for determining a volume of fluid in the body cavity from the measured harmonic components

at least one transducer assembly positioned in view of the bladder and configured to transmit ultrasound of at least one acoustic power having a fundamental frequency to the bladder, receive echoes having a harmonic frequency and the fundamental frequency reflected from surfaces associated with the bladder, and convert the fundamental and harmonic frequency echoes into fundamental and harmonic signals; and

a computer in signal communication with the at least one transducer assembly, the computer having executable signal processing software with programmed instructions to differentiate information from the fundamental and harmonic signals and to calculate the volume of the bladder and the fluid volume contained in the bladder based upon image information derived from the harmonic signals.

25. (Currently Amended) The apparatus of claim 22, wherein adapted for use where the body cavity is a bladder and the volume of fluid measured is a volume of comprises urine.

26. (Currently Amended) The apparatus of claim 25, wherein ~~in which~~ the at least one transducer assembly is adapted to transmit a beam of ultrasound sufficient to entirely sub tend the ~~entire human~~ bladder.

27. (Currently Amended) The apparatus of claim 24, wherein the programmed instructions to differentiate information from the fundamental and harmonic signals comprises signals derived from ~~further including means for selecting the received ultrasound signals from within one or more~~ predetermined depth ranges ~~and using only those signals~~ for the determination of ~~volume of fluid~~ volume in the ~~body cavity~~ bladder.

28. (Currently Amended) The apparatus of ~~claim 24 or~~ claim 26, wherein ~~where the~~ ultrasound transducer assembly comprises is a curved single active piezo-electric element, shaped to form ultrasound beams at least one of a sector of a sphere sector and a cone sector or ~~cone like sound beam~~.

29. (Currently Amended) The apparatus of claim 24 ~~28, wherein~~ ~~where~~ the ultrasound transducer assembly includes ~~is combined with a wide-angle lens distribute the ultrasound beams material so that the combination of transducer and lens create a wide sound beam to~~ approximately encompass the filled bladder.

30. (Currently Amended) The apparatus of claim 24 ~~29, wherein~~ where the transducer assembly is adapted to transmit at a fundamental ultrasound frequency and is adapted to receive the fundamental and higher harmonic signals of the transmitted frequency.

31. (Currently Amended) The apparatus of claim 27, wherein the programmed instructions to differentiate information from the fundamental and harmonic signals include averaging signals associated with the first and second power acoustic powers, subtracting the fundamental signals associated with the first power from the harmonic signals associated with



~~the second power to produce a difference signal further including means for transmitting, at the fundamental frequency, a multiplicity of different pulses to enhance the higher harmonic components in the received signals.~~

32. (Currently Amended) The apparatus of claim 24 31, wherein the difference signal derives from ~~further including means for selecting received signals from approximately a selected depth~~ of the bladder or distance.

33. (Currently Amended) The apparatus of claim 32, ~~wherein in which~~ wherein the selected depth ~~or distance~~ is beyond the posterior wall of an average filled ~~human~~ bladder.

34. (Currently Amended) The apparatus of claim 24 27, wherein the programmed instructions to differentiate information from the fundamental and harmonic signals include algorithms ~~further including means~~ for determining the scattered power of higher harmonics in the received signal and comparing the scattered power with the backscattered power in the fundamental frequency ~~in an algorithm~~ to calculate the urine volume.

35. (Currently Amended) The apparatus of claim 24 34, wherein the at least one acoustic power includes a ~~further including means for using combined pulse sequences at~~ low transmit power and ~~a~~ high transmit power to enhance bladder filling measurement and eliminate patient variation due to ~~for instance~~ obesity using combined pulse sequences arising from the low transmit and high transmit powers.

36. (Currently Amended) The apparatus of claim 24 35, wherein the combined pulse sequences arise from echo signals ~~further including means for using echo data from~~ at a depth close to the position of the average anterior bladder wall in determining volume of fluid to limit the effects of variation in the body proximal to the transducer assembly.





37. (Currently Amended) The apparatus of claim 24 36, wherein the combined pulse sequences arise from echo signals may be altered by further including means for varying the transmitted power in subsequent pulse transmissions, such that linear and non-linear echo signals from various depths can be compared to eliminate effects of patient variation.

38. (Currently Amended) The apparatus of claim 24 37, wherein the variation in fluid volumes calculations may be in the form of at least one of a in which the means for determining volume effects a volume calculation using a prior established look up table and a calibration curve.

39. (Currently Amended) The apparatus of claim 24, wherein the at least one transducer assembly include further including a display adapted to indicate a volume above a predetermined threshold level, the threshold level being determined according to a specified medical application.

40. (Currently Amended) The apparatus of claim 24 39, wherein the display indicates a further including a display adapted to indicate filling below a predetermined threshold level, the threshold level being determined according to a specified medical application.

41. (Currently Amended) The apparatus of claim 24, wherein where the at least one transducer assembly is housed separately and connected to the rest of the apparatus with a flexible cable.

42. (Currently Amended) The apparatus of claim 24, wherein where the at least one transducer assembly comprises a combination of a first acoustic active surface for optimal transmission and reception at the fundamental frequency and second acoustic active surface for optimal reception of the ~~higher~~ harmonic echo signals.



43. (Currently Amended) The apparatus of claim 24, wherein the at least one having a transducer assembly comprises including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity bladder at least one of plural angles of incidence and and/or from plural spatial locations and for providing a narrow beam direction in the dorsal direction which is used to detect the anterior and posterior bladder wall; this information is used for appropriate selection of the echo depth for proper recording of the higher harmonic echo signal.

44. (Currently Amended) A method for detecting a body cavity of a subject, measuring the volume of the body cavity and a fluid volume contained in the body cavity the volume of fluid in a human or animal body cavity using a non invasive, ultrasound echo technique, comprising the steps of :A method for measuring the volume of fluid in a human or animal body cavity using a non invasive, ultrasound echo technique, comprising the steps of : positioning a transducer assembly including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity at plural angles of incidence and/or from plural spatial locations; activating the transducers to produce transmitted ultrasound signals; detecting body cavity wall echoes from received ultrasound signals; determining, from said received signals, a body cavity height H and a depth D; determining a specific measurement configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid filled body cavity and thereby selecting an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and calculating the fluid volume according to the formula  $H \times D \times K$

positioning at least one transducer assembly in view of the body cavity;

transmitting a fundamental ultrasound frequency of at least one acoustic power to the body cavity;

receiving echoes having the fundamental ultrasound frequency and at least one harmonic frequency thereof associated with the body cavity;

converting the received ultrasound echoes into fundamental signals and harmonic signals;  
determining boundary information of the cavity from the harmonic signals;  
calculating at least one of the volume of the cavity from the boundary information and  
the fluid volume in the body cavity; and  
adjusting the calculation by comparison with at least one of a look up table and a  
calibration curve.

45. (Currently Amended) A method for detecting a body cavity of a subject, measuring  
the volume of the body cavity and a fluid volume contained in the body cavity the volume of  
fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique,  
comprising the steps of: using one or more transducers to transmit at least one ultrasound beam  
into the body such that the at least one beam encompasses a substantial portion of the target body  
cavity, the beam having at least a first frequency; receiving ultrasound echo signals from the  
body cavity; determining a measure of higher harmonic components of the first frequency in the  
received signals; and determining a volume of fluid in the body cavity from the measured  
harmonic components

positioning at least one transducer assembly in view of the body cavity;  
transmitting a fundamental ultrasound frequency of at least one acoustic power to the  
body cavity;

receiving echoes having the fundamental ultrasound frequency and at least one harmonic  
frequency thereof associated with the body cavity;

converting the received ultrasound echoes into fundamental signals and harmonic signals;  
determining boundary information of the cavity from the harmonic signals in terms of  
depth, height, and correction factor, K;

calculating at least one of the volume of the cavity from the boundary information and  
the fluid volume in the body cavity as a product of depth, height, and correction factor K; and  
adjusting the calculation by comparison with at least one of a look up table and a  
calibration curve.



46. (Currently Amended) The method apparatus of claim 24 45, wherein the correction factor K is obtainable from the look up table and the calibration curve in which the at least one beam comprises a plurality of narrow beams such as those conventionally used for ultrasound imaging.

47. (Cancelled)

